

Amendment and Response

Page 7

*Serial No. 09/978,343**Filed: October 15, 2001**Title: CANDIDA ALBICANS GENE, INTEGRIN-LIKE PROTEIN, ANTIBODIES, AND METHODS OF USE***Remarks**

The office action mailed March 21, 2003 has been received and reviewed. Claims 28, 29, 31-42, and 44-47 having been amended, claim 48 having been deleted, and claims 49-66 having been added, the pending claims are claims 28-47, and 49-66. Support for the amended and new claims is found throughout the specification and the claims as originally filed. For example, support for new claims 61-66 is found in original claim 46 and on page 7, lines 22-25 of the specification. Reconsideration and withdrawal of the rejections are respectfully requested.

The 35 U.S.C. §112, Second Paragraph, Rejection

The Examiner rejected claims 29, 32, 33, 37, 42, and dependent claims 34 and 35, under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is respectfully traversed.

Specifically, the Examiner asserted that the recitations "has" and "having" in claim 32 rendered the claim unclear. Applicants respectfully submit that, in view of the amendment of claim 32, this rejection is moot.

The Examiner also asserted that the recitation "or combinations thereof" in claims 29, 33, 37 and 42 was indefinite. Claims 29, 33, 37, and 42 have been amended to delete the recitation "or combinations thereof."

For the reasons discussed above, Applicants respectfully submit that claims 29, 32-35, 37, and 42 particularly point out and distinctly claim the claimed invention. Withdrawal of the rejection of the claims under 35 U.S.C. §112, second paragraph, is respectfully requested.

The 35 U.S.C. §112, First Paragraph, Rejection

The Examiner rejected claims 40-44 and 46-48 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the

Amendment and Response

Page 8

Serial No. 09/978,343

Filed: October 15, 2001

Title: CANDIDA ALBICANS GENE, INTEGRIN-LIKE PROTEIN, ANTIBODIES, AND METHODS OF USE

application was filed, had possession of the claimed invention. This rejection is respectfully traversed.

Specifically, the Examiner asserted that "[w]hat the specification does not disclose are antibodies to sequences other than the disclosed SEQ ID NO:2 or fragments thereof. For example, there is no disclosure of a *C. albicans* peptide with integrin-like motifs that does not have the sequence of SEQ ID NO:2 or a fragment thereof so that one cannot envision an antibody that binds to an undisclosed sequence" (page 3 of Office Action mailed March 21, 2003). Applicants respectfully disagree.

To meet the written description requirement of 35 U.S.C. §112, first paragraph, the application "must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, i.e., what is now claimed." M.P.E.P. §2163. Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, the method of making the claimed invention, *or some combination of such characteristics* (see M.P.E.P. § 2163, (emphasis added)).

Claims 40-44 are drawn to an "isolated and purified antibody to a polypeptide with integrin-like motifs encoded by a polynucleotide that hybridizes to DNA complementary to DNA having SEQ ID NO:1 under stringency conditions of hybridization in buffer containing 5x SSC, 5x Denhardt's, 0.5% SDS, 1 mg salmon sperm/25 mls of hybridization solution incubated at 65°C overnight, followed by high stringency washing with 0.2x SSC/0.1% SDS at 65°C, wherein the polypeptide with integrin-like motifs contains an I domain, two EF-hand divalent cation binding sites, a sequence sufficient to form a transmembrane domain, an internal RGD tripeptide, and a carboxy-terminal sequence having a single tyrosine residue, and wherein the antibody blocks *Candida albicans* adhesion to epithelial and/or endothelial cells."

Applicants respectfully submit that the present specification conveys with reasonable clarity to those skilled in the art that, as of the filing date, Applicants were in possession of the claimed invention antibodies. The claimed antibodies bind to a polypeptide with integrin-like motifs, a polypeptide that is defined by both physical (encoded by a

Amendment and Response

Page 9

Serial No. 09/978,343

Filed: October 15, 2001

Title: CANDIDA ALBICANS GENE, INTEGRIN-LIKE PROTEIN, ANTIBODIES, AND METHODS OF USE

polynucleotide that hybridizes to DNA complementary to DNA having SEQ ID NO:1 under stringency conditions of hybridization in buffer containing 5x SSC, 5x Denhardt's, 0.5% SDS, 1 mg salmon sperm/25 mls of hybridization solution incubated at 65°C overnight, followed by high stringency washing with 0.2x SSC/0.1% SDS at 65°C) and structural characteristics (wherein the polypeptide with integrin-like motifs contains an I domain, two EF-hand divalent cation binding sites, a sequence sufficient to form a transmembrane domain, an internal RGD tripeptide, and a carboxy-terminal sequence having a single tyrosine residue). Applicants submit that the specification provides adequate written description of polypeptides with integrin-like motifs encoded by a polynucleotide that hybridizes to DNA complementary to DNA having SEQ ID NO:1 under stringency conditions of hybridization in buffer containing 5x SSC, 5x Denhardt's, 0.5% SDS, 1 mg salmon sperm/25 mls of hybridization solution incubated at 65°C overnight, followed by high stringency washing with 0.2x SSC/0.1% SDS at 65°C (see page 5, lines 7-14, of the specification). Applicants also submit that the specification provides adequate written description for polypeptides with integrin-like motifs that contain an I domain, two EF-hand divalent cation binding sites, a sequence sufficient to form a transmembrane domain, an internal RGD tripeptide, and a carboxy-terminal sequence having a single tyrosine residue (see page 6, lines 5-11, of the specification).

Thus, Applicants respectfully submit the present specification conveys with reasonable clarity to those skilled in the art that, as of the filing date, Applicants were in possession of the invention of claims 40-44. Applicants respectfully maintain that they have satisfied the written description requirement for claims 40-44.

Amended claim 46, which depends from claim 28, is drawn to an "isolated and purified antibody to a *Candida albicans* integrin-like protein having SEQ ID NO:2, wherein the antibody blocks *Candida albicans* adhesion to epithelial and/or endothelial cells" (claim 28), "wherein the antibody blocks adhesion to epithelial and/or endothelial cells by *Candida albicans* selected from a morphological stage of *Candida albicans* development selected from the group consisting of blastospores, germ tubes, and hyphae" (claim 46). Amended claim 47, which depends from claim 34, is drawn to an "isolated and purified antibody to a polypeptide, wherein the polypeptide has the amino acid sequence of SEQ ID NO:3, and wherein the antibody blocks

Amendment and Response

Page 10

Serial No. 09/978,343

Filed: October 15, 2001

Title: CANDIDA ALBICANS GENE, INTEGRIN-LIKE PROTEIN, ANTIBODIES, AND METHODS OF USE

Candida albicans adhesion to epithelial and/or endothelial cells" (claim 34), "wherein the antibody blocks *Candida albicans* epithelial cell adhesion by at least about 50 percent" (claim 47).

The Examiner has already acknowledged that "an antibody to SEQ ID NO:2 or fragments thereof comprising SEQ ID NO:3-8 meet the written description and enablement provision of 35 USC 112, first paragraph" (see page 3, second full paragraph, of the Office Action mailed March 21, 2003). Applicants respectfully submit the present specification conveys with reasonable clarity to those skilled in the art that, as of the filing date, Applicants were in possession of the inventions of claims 46 and 47. Applicants respectfully maintain that they have satisfied the written description requirement for claims 46 and 47.

For the reasons discussed above, withdrawal of the rejection of claims 40-44, 46, and 47 under 35 U.S.C. §112, first paragraph, is respectfully requested.

The 35 U.S.C. §102 Rejection

The Examiner rejected claims 28, 29, 32, 33, 36, 37, 40-42, and 45 under 35 U.S.C. §102(b) as being anticipated by Meinke et al. (Ped. Res., 35(4/2):187A, #1106, April 1994). This rejection, so far as applied to the claims as amended, is respectfully traversed. Meinke et al. do not teach or suggest antibodies that "block *Candida albicans* adhesion to epithelial and/or endothelial cells" (claims 28, 29, 40-42, and 45). Neither do Meinke et al. teach or suggest antibodies to *Candida albicans* polypeptides consisting of SEQ ID NOs: 3-8 (claims 32, 33, 36, and 37). Thus, Meinke et al. does not set forth or make obvious each and every element of claims 28, 29, 32, 33, 36, 37, 40-42, and 45. Reconsideration and withdrawal of this rejection under 35 U.S.C. §102(b) is respectfully requested.

Summary

It is respectfully submitted that the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact

Amendment and Response

Page 11

Serial No. 09/978,343

Filed: October 15, 2001

Title: CANDIDA ALBICANS GENE, INTEGRIN-LIKE PROTEIN, ANTIBODIES, AND METHODS OF USE

Applicant's Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

| |
|--|
| CERTIFICATE UNDER 37 C.F.R. 1.8: |
| The undersigned hereby certifies that this paper is being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Assistant Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this <u>18</u> day of <u>June</u> , 2003, at <u>3:07 pm</u> (Central Time). |
| By: <u>Sandra J Truehart</u> |
| Name: <u>SANDRA J TRUEHART</u> |

June 18, 2003
Date

NAJ/sjt

Respectfully submitted,
HOSTETTER et al.

By Representatives,
Mueiting, Raasch & Gebhardt, P.A.
P.O. Box 581415
Minneapolis, MN 55458-1415
Telephone: (612) 305-1220
Facsimile: (612) 305-1228

By: Nancy A. Johnson
Nancy A. Johnson
Reg. No. 47,266
Direct Dial (612) 305-4723